Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

Claims 1 -17. Cancelled

18. (Currently Amended) A computer-based method for ~~simulation, modeling and~~ scheduling the operation of a biopharmaceutical batch process manufacturing facility, comprising the steps of:

(i) identifying a high-level process step of a biopharmaceutical production process, said high-level process step including a plurality of unit operations, each said unit operation being associated with a unit operation identifier code; wherein a scheduling cycle ~~values are defined~~ value is defined for a scheduling cycle associated with each of said plurality of unit operations;

(ii) referencing a process parameter master list for each of said unit operation identifier codes in said production process, said process parameter master list including information on individual tasks and task duration involved with each of said unit operations; and

(iii) ~~simulating~~ scheduling said process thereby generating a process time line, based upon said scheduling cycle values, that identifies initiation and completion times for each of said individual tasks for each unit operation in said production process.

19. (Currently Amended) A method as claimed in claim 18, further comprising ~~simulating~~ scheduling solution preparation relative to one or more solutions used by said individual tasks, comprising the steps of:

(i) identifying at least one solution for preparation that is needed in said biopharmaceutical production process;

(ii) determining a calculated start date for preparation of at least said one solution, wherein said calculated start date is the time when the preparation of said at least one solution should begin in order to be ready for use in said biopharmaceutical production process according to the said process time line;

(iii) assigning said at least one solution to a solution preparation vessel, wherein said preparation vessel has associated therewith solution preparation parameters;

(iv) determining the solution preparation time of said at least one solution based on the solution preparation parameters of said preparation vessel that said at least one solution was assigned to in step (iii); and

(v) generating a solution preparation time line wherein each task associated with the preparation of said at least one solution in the biopharmaceutical production process is scheduled.

20. (Previously Presented) The method of claim 19, wherein step (i) comprises the step of calculating the total volume of said at least one solution needed for one process.

21. (Previously Presented) The method of claim 19, wherein step (ii) comprises the step of calculating the latest start date for preparation of said at least one solution necessary for the preparation of said at least one solution in time for use in the biopharmaceutical production process.

22. (Currently Amended) The method of claim 18, further comprising ~~simulating the~~ scheduling of equipment preparation in said biopharmaceutical production process based upon said process time line, comprising the steps of:

(i) generating a preparation equipment protocol table, wherein each protocol in said preparation equipment protocol table includes a plurality of preparation tasks;

(ii) generating an equipment preparation procedure table, wherein each type of equipment used in said biopharmaceutical production process is associated with a plurality of protocols from said preparation equipment protocol table;

(iii) generating an equipment dimension table that includes the length, height and depth of all process equipment potentially requiring cleaning after use in said biopharmaceutical production process;

(iv) generating, using said equipment dimension table, a master list of equipment associated with said biopharmaceutical production process;

(v) generating an equipment preparation load table that includes data describing when particular soiled components from the equipment dimension table will be available for preparation during said biopharmaceutical production process based on said process time line; and

(vi) generating an equipment preparation time line, using said equipment preparation procedure table and said equipment preparation load table, for equipment preparation during the biopharmaceutical production process.

23. (Previously Presented) A method as claimed in claim 22, wherein step (vi) further uses a solution preparation time line.

24. (Currently Amended) The method of claim 18, further comprising ~~simulating~~ scheduling equipment maintenance in said biopharmaceutical production process based on said process time line, comprising the steps of:

(i) accessing an equipment data store, said data store comprising maintenance data for each of said pieces of equipment in an equipment list;

(ii) generating an equipment maintenance table using said equipment list, said equipment list comprising process equipment associated with each task in a unit operation of said biopharmaceutical production process and an equipment maintenance data store, said maintenance table including maintenance procedures, period and duration for each of said pieces of equipment; and

(iii) generating an equipment maintenance time line, which indicates a specific time and date when each of said pieces of equipment should be serviced, using said equipment maintenance table and said process time line which includes initiation and completion times for said required tasks in said unit operation of said biopharmaceutical production process.

25. (Previously Presented) A method as claimed in claim 24 wherein step (iii) further comprises using a solution preparation time line and an equipment preparation time line.

26. (Currently Amended) The method of claim 18, further comprises ~~simulating the~~ scheduling of quality control sampling and testing in said biopharmaceutical production process, comprising the steps of:

(i) defining a plurality of quality control protocols wherein said quality control protocols include a plurality of control parameters;

(ii) generating quality control protocol identifiers for each of said plurality of quality control protocols;

(iii) creating a master quality control protocol table which includes each of said plurality of quality control protocols, said associated identifier number, and said plurality of quality control parameters;

(iv) generating a master quality control sample table using said master quality control protocol table; and

(v) generating a quality control time line, using said process time line and said master quality control sample table, for quality control sampling during said biopharmaceutical production process.

27. (Previously Presented) A method as claimed in claim 26 wherein step (v) further comprises using a solution preparation time line and/or equipment preparation time line.

28. (New) The method of claim 18, further comprising defining a schedule value for cycles per process and/or cycles per batch.